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SENORX

7. 510(K) SUMMARY

MAY 28 2008

Date prepared	April 23, 2008
Name	SenoRx, Inc. 11 Columbia Aliso Viejo, CA 92656 T. 949.362.4800; F. 949.362.0300
Contact person	Eben Gordon Vice President, RA/QA SenoRx, Inc. T. 949.362.4800; F. 949.362.0300
Device name	Prostate Tissue Marker
Common name	Tissue marker
Classification name	Implantable Clip
Classification regulation	878.4300 NEU
Predicate device	Gel Mark UltraCor Biopsy Site Marker, K080698, Clearance date: 3/31/2008; NEU Fiducial Markers, K071614, Clearance date: 9/11/2007; IYE
Description	The Prostate Tissue Marker consists of a pure gold marker placed inside a 17 Ga disposable beveled needle applicator. Also contained in the needle are 2 resorbable polylactic acid/polyglycolic acid (PLA/PGA) pellets and a polyethylene glycol (PEG) plug in the needle bevel. The gold marker is intended for long-term radiographic marking of the tissue site. The pellets are visible via ultrasound for approximately 4 weeks and are essentially resorbed in approximately 12 weeks.
Indications for use	The Prostate Tissue Marker is indicated for use to radiographically mark prostate tissue.
Summary of substantial equivalence	The Prostate Tissue Marker is identical to the Gel Mark UltraCor Biopsy Site Marker (SenoRx, K080698) except for the intended use being prostate tissue rather than another soft tissue, breast. The Fiducial Marker (CIVCO, K071614) is also used to mark soft body tissues, including the prostate for the treatment of tumors. The CIVCO Fiducial Marker itself is also pure gold with approximately the same mass as the proposed device. The principle of operation, method of use, technological characteristics, and basic design are the same for the SenoRx device and similar to the CIVCO device. The indication for use, intended use, and treatment site for the Prostate Tissue Marker is a subset of that for the CIVCO device and represents a different soft tissue target for the SenoRx device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2008

SenoRx, Inc.
% Mr. Eben Gordon
VP, RA/QA
11 Columbia
Aliso Viejo, California 92656

Re: K081170
Trade/Device Name: Prostate Tissue Marker
Regulation Number: 21 CFR 878.4300
Device Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: April 23, 2008
Received: April 29, 2008

Dear Mr. Hawkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. INDICATIONS FOR USE

510(k) Number (if known): K081170

Device Name: _____ Prostate Tissue Marker _____

Indications for Use:

The Prostate Tissue Marker is indicated for use to radiographically mark prostate tissue.

Prescription Use ___X____ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081170